Executive Summary

Acute Inpatient Services (Medical-Surgical and Pediatrics)

Recommendation 1.0

The Commission should continue its regulatory oversight of acute inpatient medical-surgical and pediatric services through the Certificate of Need program.

Recommendation 1.1

The Commission recommends to the General Assembly that the current capital expenditure threshold in statute of $1,250,000 be increased to $2,500,000 for acute care hospitals.

The Commission recommends that the General Assembly continue its oversight of acute inpatient medical-surgical and pediatric services under the Certificate of Need program. In addition, the Commission recommends to the General Assembly that the current capital expenditure threshold in statute of $1,250,000 be increased to $2,500,000 for acute care hospitals. The former Planning Commission's original enabling statute (Ch. 108, Acts of 1982) set the capital review threshold at $600,000; this was amended in 1988 (Chs. 688 and 767, Acts of 1988) to $1,250,000. Beginning in 1995, the capital expenditure threshold was indexed annually to consider inflation. In a revision to CON procedural regulations effective November 6, 1995, the definition of "threshold for capital expenditures" was expanded to add the phrase "for 1995, after that to be adjusted annually by the Commission according to the Consumer Price Index-Urban (CPI-U) for the Baltimore Metropolitan Area published by the U.S. Department of Labor, and rounded off to the nearest $50,000." After indexing for inflation since 1995, the capital review threshold is now $1,450,000. The Commission believes that increasing the capital review threshold to $2.5 million for acute care hospitals would appropriately focus attention on the more expensive projects with a larger system impact.

Organ Transplant Surgery, Neonatal Intensive Care Services, and Burn Services (Specialized Services)

Recommendation 2.0

The Commission should continue its regulatory oversight of organ transplant surgery, neonatal intensive care, and burn care services through the Certificate of Need program.

Under current Maryland law, the establishment of a new organ transplant service, NICU service, or burn care service requires Certificate of Need approval. Because these services are provided by hospitals, the statute enacted in 1999 as part of HB 994 applies to any proposal to close these services. Additionally, since the 1988 imposition of the CON requirement, no hospital has applied to establish a second burn treatment center. Based on both the study and analysis performed in connection with this study, as well as the consideration of the public comments, the Commission believes it is reasonable to maintain the

current CON requirement at this time. The general consensus suggests that maintaining the CON requirement for new programs in these specialized services helps to ensure the level of regionalization needed to promote higher volumes in each program. This results in developing the highest level of skill and the best outcomes in each service. Therefore, the Commission recommends to the General Assembly that its regulatory oversight of organ transplant surgery, NICU, and burn services be maintained through the CON program.

Rehabilitation Hospital and Chronic Hospital Services

Recommendation 3.0

The Commission should continue its regulatory oversight of inpatient rehabilitation and chronic hospital services.

Recommendation 3.1

The Commission should support efforts to improve data collection regarding rehabilitation and chronic hospital services to strengthen the ability to examine need and quality issues.

The Commission recommends that the General Assembly maintain existing Certificate of Need regulation for rehabilitation and chronic hospital services. Of the eight entities submitting comments in the study, representing a cross section of Maryland's providers of acute inpatient rehabilitation services, chronic hospital services, as well as the statewide industry association, a strong consensus exists that it would be preferable to continue oversight of market entry through the CON program. The Commission also supports the need to strengthen data collection regarding rehabilitation and chronic hospital services and so that it can look further at need and quality issues. In the context of changes in the reimbursement arena for both these types of services, having relevant, reliable data will have an impact on how the Commission wants to plan for any expansion in these services areas.

Ambulatory Surgery Services

Recommendation 4.0

On an interim basis, the Commission should make no changes should be made in ambulatory surgical facilities CON policy. However, a research agenda should be developed to clarify the likely impact of policy alternatives. (See Recommendation 4-4).

Recommendation 4.1

Revisions to the MHCC Ambulatory Surgical Facility Survey should be initiated for the 2001 survey cycle, with appropriate consultation and coordination with the affected providers, to address data deficiencies.

Recommendation 4.2

In cooperation with the Department of Health and Mental Hygiene's (the Department) Office of Health Care Quality (OHCQ), research should be undertaken to define the universe of facilities in Maryland which serve as settings for invasive procedures but are not required to obtain licensure under current law and regulation. A white paper outlining the costs and benefits of expanding the scope of freestanding ambulatory surgical facility (FASF) licensure, based on this research, should be developed and distributed for review and comment. MHCC and OHCQ should consider the research and comments and formulate recommendations to the Department concerning the appropriate scope of FASF licensure.

Recommendation 4.3

A process should be initiated to develop a consensus among MHCC, OHCQ, and the regulated industry on definitions of "operating room" and "procedure room" to be employed in both CON regulation and licensure.

Recommendation 4.4

Research should be conducted to clarify the appropriate direction of CON policy reform with respect to ambulatory surgical facilities. Three areas of research focus are recommended:

- **A detailed comparative analysis of the ambulatory surgical services delivery system and the regulatory policies that have shaped those systems in a group of selected states;**

- **An in-depth analysis of the charge and cost structure of a sample of Maryland FASFs identifying the relationship between costs and charges and characteristics such as range of specialties, type of specialties, volume of procedures, and competitiveness within market service areas;**

- **A review and analysis of the implications for quality of care of Maryland policies promoting the establishment and operation of low volume, physician-office based surgical facilities.**

The reader should consider the issues and options presented in this report in a broad context. Maryland's CON policies appear to have had the effect of channeling freestanding ambulatory surgical services in the direction of many small and specialized centers. The effect of these policies on surgical use rates or system-wide health care costs is unclear, and comparisons of Maryland's unique landscape of FASFs with experience in other states or at the national level is difficult. There are some indications that the efficiency of operating room use in hospitals, in terms of average cases per room, has fallen and that Maryland's CON policies may have produced lower case

volumes per room in the FASF sector compared to that seen in most other states.

The case for regulating the supply and distribution of outpatient surgical facilities has usually rested on two major concerns and these concerns are reflected in the historic record of Maryland's consideration of CON policy in this area. The first concern is with appropriate use of surgical facilities and services and, in particular, overuse. Will continued development of ambulatory surgical facilities result in excessive use of surgical services? The second concern is with the intersection of hospital expenses for and equitable access to surgical services and how these factors are affected by varying levels of proliferation of outpatient surgical facilities, many of which will tend to have non-hospital sponsorship. Will continued development of ambulatory surgical facilities result in less efficient use of hospital and outpatient surgical center capacity, increasing the unit cost of producing surgical services? Furthermore, will the shift of surgical caseload away from the hospital setting resulting from development of outpatient surgical facilities lead to a costly and unprofitable mix of surgical patients relying on the hospital for these services while the outpatient centers dominate the provision of care to the insured population? What will be the impact of such a market segmentation on hospital financial stability and hospitals' ability to provide unprofitable but needed services and uncompensated or poorly compensated care?

On the other hand, to what extent can development of freestanding ambulatory surgical facilities be beneficial in lowering the cost of providing outpatient surgical services, by moving provision of these services out of the costly hospital setting? Do hospitals adjust their physical facilities and variable cost elements to better compete for ambulatory surgical business, or do they focus more effectively on other categories of service? There has also been strong historic support in Maryland for allowing physicians and other practitioners to engage in the provision of surgery in their private offices, at least on a limited scale, without regulatory barriers to market entry and there is undoubtedly support by consumers for the option of obtaining outpatient surgery in settings that are more personal in ambiance, more specialized in their focus on particular patient needs, and more convenient to access than most general hospitals.

Inpatient Psychiatric Services

Recommendation 5.0

The Commission recommends that Maryland continue to regulate the establishment of inpatient psychiatric facilities, services, and bed capacity through the Certificate of Need review process.

Recommendation 5.1

The Commission recommends that standards for minimum geographic and financial access to inpatient psychiatric services be adopted in the revised State Health Plan for Psychiatric Services, and that consideration be given to referencing these standards in any future clarification of statute governing the closure of hospitals or essential medical services.

Recommendation 5.2

The Commission will change the State Health Plan's current requirement for a separate Certificate of Need approval for each additional category of inpatient psychiatric service, to require an exemption from CON and to establish specific standards to met for each additional category. A statutory change may be needed, in order to clarify that, for an existing adult psychiatry service in a general hospital, the addition of child or adolescent psychiatry does not constitute a "new" medical service, requiring CON approval.

The Commission recommends that Maryland continue to regulate the establishment of psychiatric beds and facilities by means of the Certificate of Need process, and also proposes to develop certain changes and clarifications to its current regulatory authority, in the State Health Plan, to implement Recommendations 5.1 and 5.2.

The Commission is concerned that, given the particular challenges facing providers of inpatient psychiatric services in all three hospital settings, the institutions involved may choose to cease operations rather than continue to battle managed care restrictions and to absorb financial losses. Recommendation 5.1 proposes that Staff work in consultation with the Mental Hygiene Administration, HSCRC, and any other State agency or existing provider with expertise and insight on the subject, to define in regulation the criteria for minimum access to inpatient psychiatric services. Having established this baseline for geographic access to these services as part of the State Health Plan, the Commission can determine how best to apply these minimum access standards to its consideration of proposed closures of inpatient psychiatric services or facilities.

The Commission also will change the present State Health Plan's requirement that an existing psychiatric facility or general hospital with an existing inpatient service obtain an additional, separate Certificate of Need approval for each category of psychiatric care. In place of the present requirement for full CON review and approval to establish an additional service category in an existing facility or hospital psychiatric service, Staff will develop specific Plan standards to guide the review and approval of the proposed additional service through a less extensive level of administrative review, possibly as an exemption from CON. These standards will receive extensive additional public comment as part of the regulatory review process, and could include requiring the facility to provide a board-certified specialist in the service category to be added, as well as specialized staffing, and separate clinical space and programs.

Inpatient Psychiatric Services and Residential Treatment Centers for Children and Adolescents

Recommendation 6.0

The Commission should continue its regulatory over-sight of child and adolescent inpatient psychiatric and resi-dential treatment center ("RTC") services through the Certificate of Need review process.
Recommendation 6.1

The Commission should modify the State Health Plan's current requirement for a separate Certificate of Need for each additional category of inpatient psychiatric service, to require an exemption from CON, based on clinical and program standards for the proposed new service to be established in the State Health Plan for each category of inpatient psychiatric service. This change is particularly important to expanding access to inpatient psychiatric beds dedicated to the care and children and adolescents, many of which have been closed by private psychiatric facilities over the past decade.

Recommendation 6.2

The Commission should support efforts to establish an on-going comprehensive data system and bed registry for RTCs. The Commission, in partnership with the Governor's Office of Children, Youth, and Families and the Mental Hygiene Administration, should make recommendations to conduct a study on the scope, content, and ongoing administration of this database.

The Commission recommends that Maryland continue to regulate the establishment of inpatient psychiatric beds and facilities for children and adolescents, and residential treatment centers for this population, by means of the Certificate of Need process, and, proposes to develop certain changes and clarifications to its current regulatory authority, in the State Health Plan, to implement Recommendations 6.1, as discussed under a similar recommendation in Chapter 5.

This change to the existing State Health Plan for inpatient psychiatric services would remove the requirement that a hospital with an existing inpatient service obtain an additional separate CON approval for each category of psychiatric care. Staff will develop specific State Health Plan standards to guide the review and approval of proposed additional service, possibly through a CON exemption review. These standards will be included in an update and revision of the Plan, and thereby receive extensive additional public comments as part of the regulatory review process. They would include consideration of requirements for Board Eligible/Board Certified specialists in the service to be added, specialized staffing, and separate clinical space and programs.

In order to inform and support effective planning and sound CON decisions for RTC services, it is critical that a comprehensive data bank and bed registry be developed and maintained. To realize the development of such a data system will require the commitment of sufficient resources and agreements among key stakeholders on the appropriate roles of each agency. The Commission will work closely with the other responsible State agencies toward the development of the data needed to make the best use of available funding.

Intermediate Care Facilities for Addictions Treatment

Recommendation 7.0

The Commission should continue to regulate the creation of new intermediate care facilities for addictions treatment, and to expand bed capacity at existing facilities.

Proposals to develop ICFs providing alcohol and drug abuse services are reviewed based on the State Health Plan chapter that provides policies, standards, and need projections for both private and publicly-funded programs. Given that much of the treatment capacity formerly in the private sector is being redeveloped with public funds, it seems reasonable to maintain the current CON requirement at this time. Staff suggests that the Commission recommend to the General Assembly that its regulatory oversight of ICFs for alcohol and drug abuse services be maintained through the CON program.

Intermediate Care Facilities for the Developmentally Disabled

Recommendation 8.0

The Commission should continue to regulate intermediate care facilities for the developmentally disabled through Certificate of Need review, but should also develop a State Health Plan section whose rules and definitions afford procedural flexibility to any changes to facility and bed capacity proposed by the Developmental Disabilities Administration.

Although the trends for this service have been steadily downward - in bed capacity, average daily census, and overall occupancy - retaining CON review of proposed new ICF-MR bed capacity or facilities serves two important purposes. First, should circumstances ever create a situation in which private or proprietary providers attempt to enter this area, the impact of this change – on DDA's facilities, on the State budget, and on continued progress toward obtaining for each person the appropriate level and setting of care -- will be the focus of any CON review. The responsibility and the interest of the public system would be a key consideration.

In addition, keeping CON review of both proposals to increase capacity, and to decrease bed capacity or close residential facilities – even in the current circumstance of a State-only "marketplace" – brings the review of an independent agency to bear on the proposed closure or downsizing. This scrutiny and consideration provides, as it has historically in CON exemption reviews of proposed hospital closures, another perspective on the impact of the action, which can either confirm its advisability, or raise questions that DDA could not. Procedurally, the Commission (and its predecessor Health Resources Planning Commission) have worked closely with the Developmental Disabilities Administration to review proposed downsizing and facility closures expeditiously, as the Working Paper observed.

That being said, the Commission believes that accommodations for DDA's unique position in the provision of intermediate care to the developmentally disabled and mentally retarded should be considered, and could be accomplished through the development of a State Health Plan section

to guide reviews of CON applications for ICF-MR beds and facilities. In much the same way that the Commission's recently-updated State Health Plan for Intermediate Care Facilities providing substance abuse treatment distinguish between publicly-funded ("Track I") and privately-operated substance abuse treatment ("Track II") programs – and give the Track I projects and facilities significant procedural advantages, a Plan section for ICF-MR reviews could set forth different standards and procedural rules for proposals by DDA to close beds or residential centers. At the same time, criteria and considerations for any proposed private or proprietary ICF could specifically target that CON review on the impact of additional ICF-MR capacity on both DDA's programs and the State budget.

In summary, the Commission does not propose at this juncture that the Commission recommend changing the regulation of intermediate care facilities for the developmentally disabled and mentally retarded by Certificate of Need. However, the Commission, in consultation with the Developmental Disabilities Administration, will work to include Certificate of Need review standards and procedures in the State Health Plan that will recognize the unique responsibilities and circumstances of DDA in providing this service.